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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/644,265

08/19/2003

Jeffry G. Weers

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NEKTAR THERAPEUTICS
201 INDUSTRIAL ROAD
SAN CARLOS, CA 94070

EXAMINER

ALSTRUM ACEVEDO, JAMES HENRY

ART UNIT

PAPER NUMBER

1616

MAIL DATE

DELIVERY MODE

03/20/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/644,265	Applicant(s) WEERS ET AL.	
	Examiner JAMES H. ALSTRUM ACEVEDO	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/21/07.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-29,133-138,140-144 and 146-207 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 10-15, 17-18, 21-23, 26-29, 133-138, 141-144, 147-157, 159-163, 165-168, 170-180, 183-186, 188-190, and 192-207 is/are rejected.
- 7) ☒ Claim(s) 9, 16, 19-20, 24-25, 140, 146, 158, 164, 169, 181-182, 187, and 191 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/22/08; 11/21/07</u> . | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Claims 1-7, 9-29, 133-138, 140-144, and 146-207 are pending. Receipt and consideration of Applicants' Information Disclosure Statements submitted on November 21, 2007 and February 22, 2008 are acknowledged.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 11/21/07 has been entered.

Information Disclosure Statement

Applicants are advised that several foreign and non-patent literature references listed on the two IDS's submitted 11/21/07 and 2/22/08 were not provided. Other references were not considered due to the reasons stated on the IDS. If Applicants would like official consideration of the unconsidered references it is kindly requested that Applicants provide copies of these references, with citations including the publication date, and translations or description of the relevance of references not in the English language.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7, 10-12, 17-18, 26-29, 133-138, 141-143, 149-150, 151-157, 159-160, 162-163, 170-180, 183, 185-186, 192-195, and 197 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 and 14-21 of allowed application No. 11/675,073 (an allowance was mailed on February 27, 2008) (allowed '073). Although the conflicting claims are not identical, they are not patentably distinct from each other because they are overlapping in scope and mutually obvious. Both claim sets recite suspension formulations comprising perforated microstructures in which the suspension medium permeates said microstructures. The claim 2 of allowed '073 further specify that the microstructures comprise a phospholipid, nonionic detergent, nonionic block copolymer, ionic surfactant, biocompatible fluorinated surfactant, and combinations thereof. All the species recited in claim 2 of allowed '073 are recognized surfactants, as evidences, for example, by claim 7 of the instant application. The properties recited for the claimed microstructures of both the instant application and allowed '073 are the same or substantially overlapping (e.g. a

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refractive index differential of less than 0.5 is recited in '073 and refractive index differential of less than about 0.4 is recited in claim 17 of the instant application). Both sets of claims also claim that overlapping groups of bioactive agents (see, for example, claim 11 of allowed '073 and claim 193 of the instant application). Wherein specific actives are recited in the instant application, these actives represent well known and conventional examples of the same actives recited in the more general parent claims (e.g. budesonide, recited in claim 173 of the instant application, for example, is a well known conventional steroid). Furthermore, both claim sets also contain claims that recite that the microstructures comprise calcium (e.g. claim 6 of allowed '073 and claim 174 of the instant application). Regarding the suspension medium, although allowed '073 does not explicitly recite that the suspension medium is a propellant, the term "suspension medium" is defined as a propellant in paragraph 17 of the specification of allowed '073. The propellants explicitly recited in many of the claims of the instant application (e.g. claim 2) are conventional hydrofluorocarbon propellants. Claim 10 of allowed '073 indicates that the suspension medium comprises a fluorochemical. Therefore, a person of ordinary skill in the art at the time of the instant invention would have found claims 1-7, 10-12, 17-18, 26-29, 133-138, 141-143, 149-150, 151-157, 159-160, 162-163, 170-180, 183, 185-186, 192-195, and 197 *prima facie* obvious over claims 1-11 and 14-21 of allowed application No. 11/675,073.

Claims 1, 6, 10, 12-15, 133, 134, 138, and 148 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 and 12 of copending Application No. 11/317,523 (copending '523). Although the conflicting claims are not identical, they are not patentably distinct from each other because they

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are overlapping in scope with regards to the recited perforated microstructures. The cited claims of the instant application and copending '523 both recite perforated microstructures comprising a phospholipid and an active agent, wherein the phospholipid comprises greater than 10% w/w phospholipid (surfactant in the cited claims of the instant application). Both sets of cited claims recite substantially similar Markush groups of phospholipids as well (claim 5 of copending '523 and claims 12, 13, 143, and 144). The difference between claim sets is that the cited claims of the instant application recite a dispersion of perforated microstructures. The perforated microstructures of copending '523 are therefore a component of the composition recited in the cited claims of the instant application and are therefore rendered obvious by the cited claims of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 6, 10, 12-15, 21-23, 27-29, 133, 134, 138, 141, 143-144, 147-151, 156, 157, 159, 161, 165-168, 171-174, 180, 184, 188-190, 193-207 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5-7, 9, 12-15, and 18 of copending Application No. 11/317,839 (copending '839).

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are overlapping in scope with regards to the recited perforated microstructures. Both applications recite perforated microstructures comprising a phospholipid structural matrix and an active agent (e.g. budesonide), wherein the perforated microstructures have mean aerodynamic diameter less than 5 microns. It would have been obvious to a person of ordinary

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skill in the art at the time of the instant invention that the range of geometric diameters recited in claims 1 and 9 of copending '839 overlap with the range of mean geometric diameters recited in several of the cited claims of the instant application (e.g. 205-207). Both claim sets also recite perforated microstructures comprising calcium. Calcium renders magnesium obvious because both calcium and magnesium are alkaline earth metals, which readily form divalent cations. The instant application and copending '839 also recite substantially similar Markush groups of phospholipids as well (claim 7 of copending '839 and claims 12, 13, 143, and 144). The major difference between claim sets is that the cited claims of the instant application recite a dispersion of perforated microstructures. The perforated microstructures of copending '839 are a component of the composition recited in the cited claims of the instant application and are therefore rendered obvious by the cited claims of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Allowable Subject Matter

Claims 9, 16, 19-20, 24-25, 140, 146, 158, 164, 169, 181-182, 187, and 191 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Claims 1-7, 10-15, 17-18, 21-23, 26-29, 133-138, 141-144, 147-157, 159-163, 165-168, 170-180, 183-186, 188-190, and 192-207 are rejected. Claims 9, 16, 19-20, 24-25, 146, 158, 164, 181-182, 187, and 191 are objected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0664. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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/Johann R. Richter/

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